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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,661	01/23/2001	J. Richard Sportsman	LJL 35101	3789
7590	11/28/2003			
KOLISCH, HARTWELL, DICKINSON, McCORMACK & HEUSER 520 S.W. Yamhill Street, Suite 200 Portland, OR 97204			EXAMINER NICHOLS, CHRISTOPHER J	
			ART UNIT 1647	PAPER NUMBER

DATE MAILED: 11/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/768,661	SPORTSMAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Christopher Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 36-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 36-58 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \*   c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Status of Application, Amendments, and/or Claims*

1. The Amendment and Response filed 2 October 2003 has been received and entered in full. Claims 1-35 have been cancelled. Claims 36, 49, and 50 have been amended. Claim 58 has been added.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Withdrawn Objections And/Or Rejections*

3. The Objection to the Drawings as set forth at pp. 2-3 ¶4 of the previous Office Action (2 April 2003) is *withdrawn* in view of Applicant's amendments (2 October 2003).
4. The Rejection of claims **36** and **48** under 35 U.S.C. §112 ¶2 as set forth at pp. 7 ¶15-16 of the previous Office Action (2 April 2003) is *withdrawn* in view of Applicant's arguments (2 October 2003).

### *Maintained Objections And/Or Rejections*

5. Claims **36-58** are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *an in vitro method of measuring the generation or consumption of cyclic nucleotide by an enzyme selected from the group consisting of cyclases, phosphodiesterases, in the presence and absence of test compounds via the detection of polarization of emitted light*, does not reasonably provide enablement for *any other enzymes or reactions which may consume or generate cyclic nucleotides or the performance of the assay in*

*vivo*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims for the reasons as set forth at pp. 3-7 ¶5-14 of the previous Office Action (2 April 2003).

6. The Applicant traverses this rejection in the Response filed 2 October 2003 for the following reasons: **(a)** the Specification as filed supports practicing the claimed method both *in vivo* and *in vitro*, **(b)** the use of the claimed invention would not require undue experimentation, **(c)** the Specification is enabling with respect to any cyclic nucleotide and any enzyme that generates or consumes a cyclic nucleotide, **(d)** a person of ordinary skill in the art easily could generate a member of any cyclic nucleotide, **(e)** the claimed methods do not involve or require knowledge of the enzyme or other agent that consumes or generates the cyclic nucleotide, **(f)** the Specification as filed supports practicing the claimed method both *in vivo* and *in vitro*, with any reaction that generates or consumes a cyclic nucleotide, **(g)** the claimed methods may be practiced essentially without prefatory experimentation using the detailed information provided in the application regarding exemplary assay components, exemplary assay conditions, and exemplary detection methods, **(h)** Applicant is presently claiming methods of identifying compounds as modulators of reactions that generate or consume cyclic nucleotides, and **(i)** the Specification as filed provides a general method of identifying whether candidate compounds are modulators of known reactions that generate or consume cyclic nucleotides.

7. Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons:

8. On “**(a)**”, as noted by Applicant, the independent claim (36) has been amended to read *in vitro* thus this point of rejection is *moot*. The Examiner recognizes Applicant’s right to pursue other embodiments of the invention in future applications.

9. On “**(b)**”, the Specification as filed does not provide any examples, guidance, or enabling discussion of practicing the claimed method with any other reactions than adenylyl cyclase and guanylyl cyclase. However, the Examiner does accept that these two are representative of G-protein coupled receptors which may consume or generate cAMP and/or cGMP, and the rejection has been amended accordingly to include two geneses, cyclases and phosphodiesterases. Yet, the claims as written read on “a reaction that generates or consumes a cyclic nucleotide” which encompasses a massive genus of chemical and enzymatic reactions that generate or consume a “cyclic nucleotide”. Thus the claims as written present an invitation to experiment. First to identify reactions that generate cyclic nucleotides, the reactions that consume cyclic nucleotides, to establish the conditions under which both geneses may be reproduced for purposes of practicing the invention, and then performing trial and error experimentation to determine which reactions are applicable to the instant invention.

10. On “**(c)**”, the genus of reactions that generate or consume is sufficiently large as to not be taught in sufficient detail in the instant Specification to be practiced to the full extent of the claims.

11. On “**(d)**”, the Examiner is persuaded that the genus of cyclic nucleotide is sufficiently well defined in the prior art to not only encompass cAMP and cGMP.

12. On “**(e)**”, the Examiner respectfully disagrees, the very nature of the invention as claimed does require knowledge of and sufficient understanding of the mechanism of the enzyme or other

agent-derived reaction (herein chemical in nature and not defined in the Specification) that generates or consumes a cyclic nucleotide. If the skilled artisan is not aware of the enzyme or reaction then they cannot practice the invention. The Applicant asserts that said enzyme or reaction need only exist to practice the invention. However, existence is not sufficient for enablement. The Applicant must be in physical possession of the invention or describe it in such a manner as to meet the requirements of 35 U.S.C. 112 ¶1. Therefore, as noted above and the previous Office Action, the Specification has only taught how to practice the invention with enzymes more specifically cyclases and phosphodiesterase. Taken as asserted by the Applicant is an invitation to explore and first identify, then characterize any given enzyme and/or reaction to determine whether or not it is applicable to the instant invention.

13. On “(f)”, as noted by Applicant, the independent claim (36) has been amended to read *in vitro* thus this point of rejection is *moot*. The Examiner recognizes Applicant’s right to pursue other embodiments of the invention in future applications.

14. On “(g)”, as discussed above the claims as written constitute an invitation to experiment because the Specification lacks sufficient guidance to practice the full scope of the invention. The examples presented including the materials and methods of practicing the instant invention with enzymes such as cyclases and phosphodiesterases is duly noted by the Examiner and the rejection of the instant claims has been amended accordingly. However, neither guidance nor examples are provided to extent the support of the claims to any other reaction. Thus the skilled artisan is invited to explore reactions that generate or consume cyclic nucleotides and attempt to apply the instant invention through means of trial and error experimentation.

15. On “(h)”, it is noted by the Examiner what the Applicant is not claiming. However, the instant invention is not enabled to the full scope of the claims. The genres of reactions that generate or consume a cyclic nucleotide is not well defined in the specification, nor are a representative number of members of the genus presented such as to provide guidance. Thus only two enzyme genes, cyclases and phosphodiesterases are taught with sufficient guidance to be presently enabled.

16. On “(i)”, it is noted that Applicant provides modulators of cyclases and phosphodiesterases that either consume or generate cAMP or cGMP. This is duly noted. However, the issue at hand is the question of the current breadth of the claims that encompasses a massive, ill-defined genus of “reactions that consume or generate a cyclic nucleotide”. While the Examiner has accepted the Applicant’s argument in part, that sufficient guidance is given to identify and synthesize a cyclic nucleotide; sufficient guidance and examples are not present in the Specification as filed to provide the necessary disclosure to support the massive genus of enzymes and reactions as claimed. It is noted that as written, the claims read on both known and unknown enzymes and reactions, with no guidance to their mechanisms, identity, or use.

17. The rejection of claims 36-58 under 35 U.S.C. §112 ¶1 is hereby maintained.

### ***Summary***

18. Claims 36-58 are hereby rejected.

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1647

20. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.



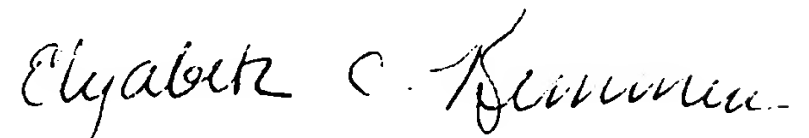
Art Unit: 1647

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



CJN  
November 24, 2003

ELIZABETH KEMMERER  
PRIMARY EXAMINER